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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,249	06/05/2002	Kozo Aoki	Q67718	1284

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EXAMINER

MORRIS, PATRICIA L

ART UNIT PAPER NUMBER

1625

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/019,249

Applicant(s)

Aoki et al

Examiner

P. Morris

Group Art Unit

1625

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 10-7-02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-12, 14-18, 20 and 21 is/are pending in the application.
- Of the above claim(s) 14-18 and 20 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-12 and 21 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2 + 10
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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DETAILED ACTION

Claims 1-12 and 21 are under consideration in this application.

Claims 14-18 and 20 are held withdrawn from consideration as being drawn to nonelected subject matter 37 CFR 1.142(b).

Election/Restriction

Applicant's election without traverse of Group II and compound 41 of Example 1 in Paper No. 9, filed October 7, 2002 is acknowledged.

Claims 14-18 and 20 are drawn to multiple uses.

This application has been examined with respect to the elected compound and expanded to include a genus wherein A is methylene, L is C₄ - C₈ alkylene, X is O, S or CH₂, and m is 0 or 1, as set forth in claim 1, exclusively.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was

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commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-12 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Gregory et al. (Bioorganic & Med Chem. Letts., 10(6), 2000, 527-529) and Giani et al.(US 4,971,980).

Gregory et al. and Giani et al. teach analogous compounds that differ by homology. For example, 2-(4-piperidin-1-ylbutyl)benzimidazole in example 4 of Giani differs only in having a C₄ alkylene chain. The prior art compounds differ from the compounds claimed herein as alkyl homologs of the claimed compounds. For example, the instant compounds wherein n is 4 are the next adjacent homologs of the compounds of Gregory et al. One having ordinary skill in the art would have been motivated by the disclosure of the prior art compounds to arrive at other compounds within the claimed genus. The motivation to make these compounds is their close structural similarities to the disclosed compound. Note that the disclosed compounds of the references have pharmaceutical activity, thus the skilled artisan would expect such structurally similar compounds to possess similar properties. While homology is considered to be present even if true "homology" is not present, such does not defeat the prima facie case of obviousness

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raised by the art. Attention, in this regard is directed to In re Druey et al., 50 CCPA 1538, 319 F.2d 237, 138 USPQ 39, wherein Judge Worley, delivering the Court's opinion, stated:

"We need not decide here whether the compounds in question are properly labeled homologues. It appears to us from the authorities cited by the solicitor and appellants that the term homologue is used by chemists at times in a broad sense, and at other times in a narrow or strict sense. The name used to designate the relationship between the related compound is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound." 50 CCPA 1541.

Also, as the Court stated in In re Payne et al., 606 F.2d 302, 203 USPQ 245 at 255 (CCPA 1979):

"the name used to designate the relationship between related compounds is not necessarily controlling; it is the closeness of that relationship which is indicative of the obviousness or unobviousness of the new compound."

In addition, any question of why would one conceive and use the similar compounds (*i.e.* "motivation") is answered by the Court in In re Gyurik et al., 596 F.2d 1012, 201 USPQ 552 at 557.

"In obviousness rejections based in close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness, rises from the expectation that compounds similar in structure will have similar properties."

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, 10, 12 and 21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Aryl could be read as aromatic. Some aromatic groups are heterocyclic. Therefore, the indefiniteness of claims 7, 10 and 21 causes overlap.

Applicants claim all aryl radicals in R¹³. Applicants' exemplification cannot be seen to provide adequate representative support for such a claim.

There are no carbon limits on aryl in claim 7, 10 and 21.

The definition of aryl is varied, note the footnotes on pages 134 USPQ 301-304 of In re Sus, for multiple varied definitions of aryl.

Therefore, applicants need to indicate in the claims what they intend by aryl.

All aryl radicals are not supported in the specification, yet they are claimed here. Applicants could resolve this point in the claim by indicating aryl is phenyl, naphthyl, or indicate a carbocyclic aryl of 6 to 10 carbon atoms.

A Markush listing of specific intended, producible rings for aryl is suggested in claims 7, 10 and 21.

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Applicants claim all acyl radicals in R^2 and R^{12} in claims 1 and 7. Applicants' exemplification cannot be seen to provide adequate representative support for such a claim.

The expressions " R^3 and R^{13} represents one or more....nitrogen atom" and "acyl" are employed with considerable abandon throughout claims 1, 7, 12 and 21 with no indication given as to what the substituents or acyl groups really are.

One should be able, from a reading of the claims, determine what that claim does or does not encompass.

Why? Because that claim precludes others from making, using, or selling that compound for 20 years. Therefore, one must know what compound is being claimed.

The unknown substituents and prodrugs are so broad that they cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception of the intended substituents and acyl groups should not be the role of the reader. Applicants should, in return for a 20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 USC 112, first paragraph. If you (the public) find that it works, I claim it, is not a proper basis of patentability. In re Kirk, 153 USPQ 48, at page 53.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term containing in claims 1 and 12 is open ended because it allows for the inclusion of other active ingredients.

The claims measure the invention. United Carbon Co. V. Binney & Smith Co., 55 USPQ 381 at 384, col. 1, end of 1st paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockheed Aircraft Corp. v. United States, 193 USPQ 449, "Claims measure invention and resolution of invention must be based on what is claimed".

The C.C.P.A. in 1978 held "that invention is the subject matter defined by the claims submitted by the applicant. We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 USPQ 11, at 15.

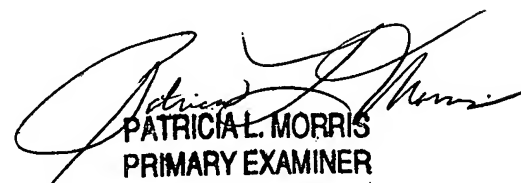
Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Morris whose telephone number is (703) 308-4533.

plm

December 16, 2002


PATRICIA L. MORRIS
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GROUP 120